

U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT LBNL-ARC-98-05

OF

LAWRENCE BERKELEY NATIONAL LABORATORY

BERKELEY, CALIFORNIA

JANUARY 12-16, 1998

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1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit LBNL-ARC-98-05, the audit team determined that the Lawrence Berkeley National Laboratory (LBNL) is marginally effective in implementing the Office of Civilian Radioactive Waste Management (OCRWM) QA program in accordance with the U.S. Department of Energy (DOE) OCRWM Quality Assurance Requirements and Description (QARD) document, DOE/RW-0333P, Revision 7; and LBNL's implementing procedures. QA Program Elements 1.0, 6.0, 16.0, 17.0 and Supplement II were considered effective with Element 2.0 determined to be marginally effective. Elements 4.0, 5.0, 7.0, and Supplements I and V were not effectively implemented. Implementation of Element 12.0 and Supplement III were considered indeterminate. There was no implementation of Element 15.0, and currently no activities implement Elements 3.0, 8.0, 9.0, 10.0, 11.0, 13.0, 14.0, 18.0 and Supplement IV.

Due to the concerns with a lack of documented technical reviews of Scientific Notebooks (SN) prior to producing final reports, incomplete documentation and resolution of review comments, the questionable status of Measuring and Test Equipment (M&TE), and incomplete documentation of software codes, the end results presented in deliverables and data submitted to the technical data base may be adversely affected. Evaluation of individual technical products will be conducted during performance based audits.

The audit team identified deficiencies during the audit that resulted in the issuance of seven OCRWM Deficiency Reports (DR) described in Section 5.5.2. In addition, deficient conditions discovered in QARD Elements 4.0 and 7.0 have been submitted for inclusion in a project Corrective Action Report (CAR) VAMO-98-C-005, issued to the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O).

There were two deficiencies identified by the audit team and corrected prior to the postaudit meeting. These conditions are described in Section 5.5.4 of this report. Additionally, there were four recommendations resulting from the audit, which are detailed in Section 6.0 of this report.

2.0 SCOPE

The audit was conducted to evaluate the adequacy, compliance, and effectiveness of implementation of the OCRWM QA Program at LBNL.

The following QA program elements/requirements were evaluated during the audit, in accordance with the approved audit plan:

QA PROGRAM ELEMENTS/REQUIREMENTS

1.0	Organization
2.0	Quality Assurance Program
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	Quality Assurance Records
Supp. I	Software
Supp. II	Sample Control
Supp. III	Scientific Investigation
Supp. V	Control of the Electronic Management of Data
Appendix C	Mined Geologic Disposal System (amplifications to above elements/requirements, as applicable)

The following QA program elements were not reviewed during the audit since LBNL currently has no activities to which these elements apply:

3.0	Design Control
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test and Operating Status
18.0	Audits
Supp. IV	Field Surveying

3.0 AUDIT TEAM AND OBSERVERS

The following is a list of audit team members, their assigned areas of responsibility, and observers:

<u>Name/Title/Organization</u>	<u>QA Program Elements/Requirements.</u>
Stephen D. Harris, Audit Team Leader, OQA	Supplements I and V.
Kristi A. Hodges, Auditor, OQA	5.0, 6.0, 15.0, 16.0, App.C
James C. Mattimoe, Auditor, OQA	1.0, 2.0, 4.0, 7.0, 12.0, App.C
Edward P. Opelski, Auditor, OQA	17.0, Supplements II and III
John F. Pelletier, Auditor, OQA/LLNL	Supplement I
James M. Ziemba, Auditor, OQA/LBNL	Supplement I





4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED



The preaudit meeting was held on January 12, 1998, at the LBNL offices located in Berkeley, California. Daily debriefing and coordination meetings were held with LBNL's management and staff, and daily audit team meetings were held to discuss audit status. The audit was concluded with a postaudit meeting held on January 16, 1998, at the LBNL offices in Berkeley, California. Personnel contacted during the audit are listed in Attachment 1. The list includes those who attended the preaudit and postaudit meetings.





5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, the QA program implemented at LBNL is marginally effective for the scope of this audit with the following exceptions: QA Program Elements 4.0, 5.0, 7.0, and Supplements I and V were considered unsatisfactory.

No additional deficiency documents associated with Elements 4.0 and 7.0 were generated during the audit; however, additional instances of noncompliance identified during the audit, in these elements, have been included in CAR VAMO-98-C-005. Element 5.0 was determined to be unsatisfactory based on identified deficiencies in procedures that are to implement Supplements I, III and V. In addition, QIP-5.2, Revision 1, MOD 0,  Preparing Quality and Technical Implementing Procedures,  allows technical procedures to be included in SNs without being subject to QARD Sections 2.0 (2.2.10), 5.0 and 6.0 requirements for implementing documents. Supplement I was considered unsatisfactory because LBNL-SI.0, Revision 2, MOD 0,  General Software Quality Assurance,  contained insufficient detail for implementing this element. The unsatisfactory determination was also based on an existing DR, LBNL-98-D-024, issued prior to the audit, documenting incomplete documentation of software codes. The implementation of Supplement V was considered unsatisfactory in that no procedure has been prepared.

Element 2.0 was determined to be marginally effective based on implementation deficiencies associated with qualification of personnel, documentation and resolution of mandatory comments, and incomplete requirements matrix preparation and update. Overall implementation of Element 12.0 was considered indeterminate, as further evaluation is needed to determine whether the associated DR condition documented during the audit extends to other activities. Procedure related deficiencies were identified in LBNL QIP-SIII.0, Revision 1, MOD 1,  Scientific Investigations,  which is to implement Supplement III requirements. The overall implementation of Supplement III was considered indeterminate, as the impact on completed deliverables could not be assessed without further evaluation. Although a DR was generated for failure to meet the requirements

of AP-17.1Q, Revision 0,  Record Source Responsibilities for Inclusionary Records,  implementation of YMP-LBNL-QIP-17.0, Revision 1, MOD 0,  Submitting Records to the YMP-LBNL Records Processing Center,  effectively meets QARD Program Element 17.0 requirements.

The results for each program element evaluated are contained in Attachment 2, Summary of Audit Results.

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders, immediate corrective actions, or related additional items resulting from this audit.

5.3 QA Program Audit Activities

A summary table of audit results is provided in Attachment 2. The details of the audit evaluation, along with the objective evidence reviewed, are contained within the audit checklists. The checklists are kept and maintained as QA Records.

5.4 Technical Audit Activities

There were no technical audit activities evaluated during this audit.

5.5 Summary of Deficiencies

The audit team identified eleven deficient conditions during the audit which resulted in seven DRs. Procurement deficiencies have been added to CAR VAMO-98-C-005 issued to the CRWMS M&O. Two additional deficiencies were corrected prior to the post-audit meeting.

Synopses of deficiencies documented in the CAR, DRs, and those corrected during the audit, are presented below. The CAR and DRs have been transmitted under separate letters.



5.5.1 Corrective Action Requests (CAR)



Deficient conditions discovered prior to and during the audit relative to QARD Elements 4.0 and 7.0 (Procurement) have been included in CAR VAMO-98-C-005 issued to the CRWMS M&O. The additional deficiencies identified during the audit include: A subcontract to Keithley Instruments, Inc. was modified without required review or Office of Quality Assurance (OQA) representative concurrence; a subcontract to Sierra Instruments, Inc. was reviewed after the issue date, contrary to requirements, and was submitted to a location not on the OCRWM Qualified Suppliers List (QSL); two subcontracts to Campbell Scientific

were reviewed after the issue date; and a subcontract to Scott Specialty Gasses was submitted to a location not on the QSL. These conditions will be tracked and closed through resolution of this corrective action document.



5.5.2 Deficiency Reports (DR)

DR YM-98-D-029

LBNL-QIP-SIII.0, Revision 1, MOD 1,  Scientific Investigation,  is deficient in the following areas:

- 1) There are five Technical Implementing Procedures (TIP) approved for LBNL use; however, these do not address the majority of quality-affecting activities at LBNL. Notebook procedures are written and used when a repetitive investigation process is required, but is not sufficiently complex to warrant development of a TIP. This position does not coincide with the QARD glossary definition for SNs. Furthermore, the procedures prepared in SNs are written to meet the requirements of QARD Supplement III, but not those of Sections 2.0 (2.2.10), 5.0 or 6.0.
- 2) QIP-SIII.0 permits the user to document deviations from standardized procedures in SNs, which does not meet QARD Section 5.2.4.
- 3) QIP-SIII.0 addresses the qualification of unqualified data which is not a function of LBNL and is not in accordance with YAP-SIII.1Q, Revision 1,  Qualification of Unqualified Data. 
- 4) There is no objective evidence of a technical review of SNs used to document scientific investigations supporting LBNL deliverables.

DR YM-98-D-030

Document Review/Comment Resolution (DRCR) forms for three selected documents were evaluated. Forms for two of the reviews indicated no mandatory comments, although comments were annotated on attached draft documents. These annotated comments do not meet the requirements of QARD Section 2.2.10; or QIP-6.1, Revision 2, MOD 0,  Document Review,  as they included technical comments that were perceived as mandatory in nature. Forms for two document reviews contained mandatory comment responses without reviewer concurrence, as required. In addition, two incidents of inadequate response to review comments were identified.

DR YM-98-D-031

QARD Section 2.2.12 requires the Affected Organization (AO) to establish and verify minimum education and experience requirements for personnel performing work subject to the QARD. Based on review of qualification records, only education is verified by LBNL. Although reviewed personnel requisitions detail essential selection criteria, including required experience, LBNLYMP General Position Descriptions include optional requirements for experience.





DR YM-98-D-032

The QARD requirements matrix, as required by Section 2.2.1C.3, has not been updated to meet the current revision of the QARD. In addition, seven LBNL implementing procedures have been revised, but the changes have not been reflected in this matrix nor were they submitted to OQA for review, as required.



DR YM-98-D-033

LBNL personnel used M&TE to collect data in support of the Drift Scale Test (DST) for Acoustic Emissions and Ground Penetrating Radar Studies. The Acoustic Emissions equipment was calibrated by a supplier not on the QSL and the Ground Penetrating Radar equipment was not calibrated. This deficiency had been documented on a draft DR prior to the audit but had not been issued.

DR YM-98-D-034

AP-17.1Q, Revision 0,  Record Source Responsibilities for Inclusionary Records,  applies to all AOs. By DOE letter of direction, AOs were to cancel all internal records management procedures and implement this AP. LBNL had not canceled their procedure YMP-LBNL-QIP-17.0, Revision 1, MOD 0,  Submitting Records to the YMP-LBNL Records Processing Center,  which does not meet all of the requirements of AP-17.1Q. There was also no objective evidence to indicate implementation of AP-17.1Q.

DR YM-98-D-035

QIP-SI.0, Revision 2, MOD 0,  General Software Quality Assurance,  does not implement Supplement I requirements in many cases, but only reiterates the words of this section of the QARD. This procedure needs to have more step-by-step methods described such that implementers can perform the procedure the same way each time.







In addition to the above DRs, another deficient condition is being evaluated. LBNL has not issued a procedure to implement QARD, Supplement V. Guidance on implementation of Supplement V requirements is being formulated within the OQA. This issue will be revisited once determination has been made for direction on the project.

5.5.3 Performance Reports (PR)

None.



5.5.4 Deficiencies Corrected During the Audit

Deficiencies which are considered isolated in nature and only requiring remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

1. QIP-2.1, Revision 2, MOD 0,  Qualifying Personnel,  requires a Training/Qualification form to include the name of the person verifying university education for personnel. One form was discovered that indicated  Registrar's Office ; however, did not list an individual by name. The university was contacted and the education reverified. A new form was generated which listed the name of the person in the Registrar's Office with whom the education was verified.
2. AP 17.1Q, Revision 0, ICN 0,  Record Source Responsibilities for Inclusionary Records,  requires lists of references cited in project reports to be submitted to the Technical Information Center (TIC). Prior to the audit, this list had not been submitted. A compiled list of references cited in LBNL reports from the previous two years and up to October 1997 was submitted to the TIC during the audit.

5.5.5 Follow-up of Previously Identified CARs and DRs

Follow-up of YM-97-D-048 was performed during the audit. The DR identified two LBNL SNs that do not comply with the QARD and LBNL procedure requirements for SNs. There was insufficient corrective action to permit this DR to be closed.





Follow-up of LBNL-98-D-011 was performed. The DR indicates that LBNL personnel did not complete a Technical Data Information Form for data included in report  Three Dimensional Thermo-Hydrologic Mountain-Scale UZ Model.  An acceptable response to this DR was



submitted to OQA during the audit. No other instances of this condition were identified during the audit.

Follow-up of LBNL-98-D-024 was performed. The DR states that TOUGH2 computer code modules had been used in Quality Affecting work prior to completion of all required software verification documentation and software identification forms. No corrective action had been performed to permit closure of this DR.

6.0 RECOMMENDATIONS

The following recommendations resulted from the audit and are presented for consideration by the LBNL's management.

1. QIP 5-2, Revision 1, Mod. 0,  Preparing Quality and Technical Implementing Procedures,  Paragraphs 3.3.8 and 3.3.9, require a management review, in addition to the two Technical and one Engineering Assurance (EA) reviews of LBNL procedures. However, this review is not required to be documented on the DRCR form. It is recommended that the procedure be revised to require the management review documentation to be consistent with that of the Technical and EA reviews.
2. Evaluate the DRs that were open during and generated as a result of this audit, to determine whether LBNL products, as described in QARD Appendix C.2.5, have been impacted and therefore require generation of Nonconformance Reports in accordance with YAP 15-1Q, "Control of Nonconformances."
3. YMP-LBNL-QIP-2.1, Revision 2, Mod. 2,  Qualifying Personnel,  Paragraph 3.3.6, requires the Applicable Manager to evaluate and assess the need for additional indoctrination and training, when assignments, positions, and implementing documents change, and assure that the training of affected personnel is completed prior to the affected work being performed. QARD Section 2.2.12 G and H contain the same requirements.

LBNL generated deficiency report LBNL-97-D-01 in January of 1997. This DR documented noncompliance with this requirement and specifically addressed post-effective reading. The YMP-LBNL Reading Assignment Statement was revised to address post-effective reading. Additionally, the YMP-LBNL Training Assignment Form is used to document the requirement for the Applicable Manager to evaluate and assess the need for additional training. However, the use of these forms is not addressed, nor are they included in LBNL-YMP-QIP-2.1, Revision 2, MOD 0,  Qualifying Personnel. 

It is recommended that LBNL-YMP-QIP-2.1 be revised to address the use and incorporate the Reading Assignment Statement and the Training Assignment Form.

4. LBNL has two DRs that document deficiencies in its software QA process. The configuration management process has not been maintained for existing software which indicates essential software documentation has not been completed or maintained for existing baseline documents. In addition, the procedure does not adequately implement the QARD. The process for performing work needs to be clearly established before the specifics of implementation can be effectively accomplished. Resolution of both DRs is critical to achieving an effective software QA program; however, it is recommended that priority be placed on addressing the procedure-related issues of DR LBNL-98-D-035 in order to ensure the adequacy of implemented corrective actions for DR LBNL-98-D-024.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit

Attachment 2: Summary of Audit Results for Procedural Compliance Evaluations

ATTACHMENT 1

Personnel Contacted During the Audit

<u>Name</u>	<u>Organization/Title</u>	<u>Preaudit Meeting</u>	<u>Contacted</u>		<u>Postaudit Meeting</u>
			<u>During Audit</u>		
Bodvarsson, G.	LBNL/Dept. Head	X			X
Fissekidou, V.	LBNL/EA	X	X		X
Hastings, C.	LBNL/Proj. Admin.	X		X	
Hayes, L.	M&O/TRW/NEPO Mgr.	X			
Jackson, J.	LBNL/EA/Contracts	X	X		X
Mangold, D.	LBNL/EA	X	X		X
McClung, I.	LBNL/QA Staff Assistant	X			X
O'Shea, C.	LBNL/QA Staff Assistant	X			X
Pelletier, J.	OQA/Site Representative	X	X		X
Simmons, A.	LBNL/UZ/SZ Point of Contact				X
Tsang, Y.	LBNL/Principal Investigator		X		
Wang, J.	LBNL/Principal Investigator		X		
Ziemba, J.	OQA/Site Representative	X	X		X

LEGEND:

EA Engineering Assurance
 LBNL Lawrence Berkeley National Laboratory
 NEPO Natural Environment Program Operations
 OQA Office of Quality Assurance
 SZ Saturated Zone Hydrologic Modeling
 UZ Unsaturated Zone Hydrologic Modeling

ATTACHMENT 2
Summary of Audit Results
For Procedural Compliance Evaluations

ELEMENT	IMPLEMENTING DOCUMENTS	DETAILS (Checklist)	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1	QIP-1.0, R.2, M 0	pg. 1	N	N	SAT	SAT	SAT
2	QIP-2.1, R.2, M 0 QIP-6.1, R.2, M 0	pg. 2-10 pg. 25-28	CDA #1 LBNL-98-D-030 LBNL-98-D-031 LBNL-98-D-032	REC #3	MARGINAL	UNSAT	MARGINAL
4 & 7	QIP-4.0, R. 2, M 0	pg. 11-14	VAMO-98-C-005	N	SAT	UNSAT	UNSAT
	QIP-4.1, R. 2, M 0	pg. 15	VAMO-98-C-005	N	SAT	UNSAT	
	QIP-4.2, R. 1, M 0	pg. 16	VAMO-98-C-005	N	SAT	UNSAT	
5	QIP-5.2, R. 1, M 0	pg. 17-24	LBNL-98-D-029 LBNL-98-D-035 LBNL-98-D-036	REC #1	UNSAT	SAT	UNSAT
6	QIP-6.0, R. 1, M 1	pg. 29-31	N	N	SAT	SAT	SAT
	QIP-6.1, R. 2, M 0	pg. 25-28	LBNL-98-D-030	N	SAT	UNSAT	
12	QIP-12.0, R. 1, M 1	pg.32-37	LBNL-98-D-033	N	SAT	UNSAT	INDET
15	YAP-15.1Q, R.3 I1	pg. 38-39	N	REC #2	SAT	NI	NI
16	AP-16-1Q, R. 2	pg. 40-42	N	N	SAT	SAT	SAT
	AP-16.2Q, R. 2	pg. 43	N	N	SAT	NI	
	AP-16.4Q, R. 0	pg. 44-45	N	N	SAT	NI	

ELEMENT	IMPLEMENTING DOCUMENTS	DETAILS (Checklist)	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
17	QIP-17.0, R. 1, M 0	pg. 46-55	LBNL-98-D-034	N	SAT	SAT	SAT
	AP 17.1Q, R. 0	pg. 46-55	CDA #2 LBNL-98-D-034	N	SAT	NI	
Supl. I	QIP-SI.0, R. 2, M 0	pg. 56-71	YM-98-D-035	REC #4	UNSAT	UNSAT	UNSAT
Supl. II	QIP-SII.0, R. 1, M 0	pg. 72-79	N	N	SAT	SAT	SAT
Supl. III	QIP-SIII.0, R. 1, M 1	pg. 80-97	LBNL-98-D-029	N	UNSAT	SAT	INDET
	QIP-SIII.3, R. 1, M 0	pg. 98-102	N	N	SAT	SAT	
Supl. V	No procedures	pg. 103	YM-98-D-036	N	UNSAT	UNSAT	UNSAT

Legend:

CDA Corrected during audit
N/A Not applicable
N/I Not Implemented
N None

REC Recommendation
SAT Satisfactory
UNSAT Unsatisfactory